Exhibit 2

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

PETER POE, *et al.*,

Plaintiffs,

v.

GENTNER F. DRUMMOND, *et al.,*

Defendants.

No.23-cv-00177-JFH-SH

SUPPLEMENTAL DECLARATION OF MICHAEL K. LAIDLAW, M.D.

SUPPLEMENTAL DECLARATION OF MICHAEL K. LAIDLAW, M.D.

I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. I submit this rebuttal declaration to respond to the declarations and rebuttals of Drs. Janssen, Adkins, Turban and Antommaria. I have not addressed every point made by the plaintiffs' experts in their declarations. Rather, I have focused on specific examples from their declarations to highlight aspects of the problems with gender affirmative therapy (GAT) for minors. I reserve the right to revise or add to the opinions made in my declaration.

2. Dr. Janssen states that "Dr. Laidlaw has neither had the training nor the certification and licensure to weigh in as an expert on the appropriateness of a mental health assessment or treatment plan." (Janssen rebuttal, par. 15) He goes on to write that "expertise in the treatment of transgender people requires experience in the care of transgender people, which Dr. Laidlaw does not possess." (Id.). Dr. Janssen's statements are peculiar. I have never claimed to be an expert in mental health alone. I am an expert in endocrinology. And as an endocrinologist, I must routinely analyze the psychological and mental health of patients, since their conditions can be caused by hormone excess or deficiency. For example, if a psychiatrist refers a patient to me with an anxiety disorder, and the psychiatrist believes this may be due to a thyroid condition (which can and does occur), I must make an independent medical assessment by obtaining a history, physical, laboratory results, and/or imaging tests before coming to both a diagnosis and treatment if necessary.

3. Dr. Janssen at times discusses the "care of transgender people" as though it is somehow divorced and separate from the rest of medical and endocrine care. As I stated in my declaration, quoting from our letter to the editor of The Journal of Clinical Endocrinology and Metabolism, "Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB) and high-dose cross-sex (HDCS) hormones" (Laidlaw et al., 2019) (Laidlaw decl, par 20). To phrase it in a different way, people who identify as transgender and receive hormones to alter their bodies develop endocrine conditions that require monitoring and medical follow-up. Endocrinology is therefore widely acknowledged to be important when it comes to GAT. Dr. Janssen's own original declaration cites as authoritative a "clinical practice guideline from the Endocrine Society" that "provides similar widely-accepted protocols for the medically necessary treatment of gender dysphoria." (Janssen decl., par. 50). Our letter to the editor was critical of that very same guideline.

4. What is unique about GAT is that hormones are being administered to alter the human body based on a psychological condition and not a physical condition. Even more than that, hormones

are being administered in high doses to produce the endocrine conditions of hyperandrogenism and hyperestrogenemia, which are hormone imbalance conditions that endocrinologists like me routinely treat or resolve. So, I am very familiar with these conditions as my daily work involves the diagnosis and treatment of hormone imbalances. Also, GnRHa (puberty blocking medications) are given to cause the endocrine condition hypogonadotropic hypogonadism which results in deficiencies of sex hormones and stops normal adolescent pubertal development. This is another endocrine condition that endocrinologists diagnose and treat.

5. In addition to diagnosing and treating endocrine conditions like those caused by GAT, I also have a patient who underwent GAT as an adolescent and is now suffering complications from hormones and genital surgery to alter his body. He regrets his decision and is referred to as a detransitioner. So, I have firsthand clinical knowledge of what happens when a person is misdiagnosed and is now experiencing lifelong negative health effects because of GAT.

6. I also find their insinuation to be indefensible that unless a physician actively provides GAT they are unable to comment as an expert on the subject. The very nature of science and medicine is that it is to be debated, interrogated, and continued to be investigated in the search of truth and the best possible treatments for patients. As such both the providers of GAT and those that are critical of such treatments must be allowed to debate the case for and against in order to maximize the benefits for gender dysphoric patients and minimize the harms. To exclude critical voices is a dangerous suggestion. I am an expert in all of the hormonal modalities that are used in GAT and as such I am very aware of the potential risks of altering human physiology such as is promoted by GAT. Should the critics of lobotomy have been silenced, for example, then this harmful practice might remain in widespread usage today (Caruso and Sheehan, 2017).

7. Both Dr. Janssen and Dr. Turban take issue with the interpretation of objective facts from Dhejne's data (Janssen rebuttal, par 47) (Turban rebuttal, par 14). The Dhejne team made extensive use of numerous Swedish database registries and examined data from 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery (Dhejne et al., 2011). They used population controls matched by birth year, birth sex, and reassigned sex. When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden. Neither Dr. Janssen nor Dr. Turban dispute these facts in their rebuttals.

8. Instead, Dr. Janssen appeals to the author's subjective opinion about the data (Janssen rebuttal, par 47). A principle of reviewing scientific studies is an awareness that a study provides 1) methods of how the study is conducted and 2) data resulting from the conduct of the study. Both of these sections of a study are intended to contain objective facts such that 1) anyone can interpret the data and critique the methods used to obtain such data, and 2) anyone can repeat the study under similar conditions to see if they obtain similar results.

9. The study author's opinions (even Dhejne's) are simply that, opinions. They are a subjective interpretation of the data. They are subject to biases, as are anyone's opinions. In other words, the study's author's statement doesn't amount to science or preclude anyone else from forming a different or even opposite opinion as Drs. Janssen and Turban imply.

10. Drs. Janssen and Turban do not challenge that a comprehensive study of 30 years' worth of data showed remarkably high rates of completed suicide, psychiatric hospitalization and mortality compared to the socially liberal population of Sweden. The suicide rate was 19 times the general population. While it is true that it is not known if GAT increased these risks, it also is not proven that GAT decreased the risks either.

11. What we are left with are statistics that show very high rates of morbidity and mortality in spite of both hormonal and surgical interventions that are supposedly intended to prevent such occurrences, and are widely advertised as successfully doing so. Given that suicide occurs in the context of psychological conditions, and particularly depression, in my opinion it is more likely that untreated psychological comorbidities, possibly compounded by negative psychological effects of high dose hormones and post operative regret, led to higher rates of completed suicide as compared to the general population (Hirschfeld and Russel, 1997).

12. Another prominent study in which persons receiving GAT had died of suicide is the Chen study which I describe in my declaration (Laidlaw decl, section III.D.). Briefly, this arm of the study included 315 adolescents aged 12 to 20 years old who were taking high dose hormones of the opposite sex (Chen et al., 2023). The study was not randomized and had no control group. The authors reported that 2 out 315 subjects died by suicide. The authors also reported "[t]he most common adverse event was suicidal ideation" in 11 subjects. Oddly, responding to my citation of Chen, Dr. Turban is not particularly curious and is even dismissive of the increase in suicidality and suicide deaths stating that "death from suicide is not a recognized side effect of gender-affirming medical care" (Turban decl, par 15). Simply because practitioners of GAT do not "recognize" these outcomes does not mean the evidence can be dismissed.

13. Dr. Turban means to cast doubt that I have obtained consent forms for this study via my colleague's FOIA request, stating about them, "the consent forms from this study, which Dr. Laidlaw *supposedly* received through FOIA requests" (Turban decl, par 15) (emphasis mine). Again, Dr. Turban's dismissiveness and lack of concern about a potentially misleading consent form in ongoing NIH funded research for GAT is troubling. I have attached the consent forms and the letter responsive to the FOIA request appeal from DHHS dated April 17, 2020. I note again that death by suicide (or by any cause) is not listed in the consent forms and was not disclosed as a possible outcome to participants.

14. It's not surprising that Dr. Adkins is aware of the practices regarding GAT that occur at her own institution or that are promoted by WPATH and the Endocrine Society Guideline (ESG) (Adkins rebuttal, par 5-6). However, it is concerning that Dr. Adkins is not apparently aware of the actual practices that occur in Oklahoma and indeed other parts of the country. It's one thing to describe an ideal of patient care based purely on guidelines. It's quite another thing to examine the care of the actual patients involved. This is one reason why I read through each of the plaintiff's declarations to begin a preliminary review of their individual cases.

15. Not only has Dr. Adkins not reviewed any of the plaintiffs' cases as described within their declarations, but also neither have Drs. Janssen, Turban, and Antommaria (Declarations and Rebuttals of Adkins, Jensen, Turban, and Antommaria). Nor, as far as I can tell, have they reviewed the "detransitioner" affidavits filed in this case. As I stated in my declaration, because the rate of desistance for young people is very high, many adolescents can be permanently harmed by GAT because of improper diagnoses and/or deficient evaluation of psychiatric comorbidities. (Laidlaw decl, section III.F.)

16. Dr. Adkins and the other experts should be eager to examine the medical records of all the plaintiffs in order to ensure that the various medical and mental health professionals involved have adhered to the WPATH/Endocrine Society recommendations for each plaintiff. This is especially true if Dr. Adkins "cannot speak to the practice of every gender clinic in the country" (Adkins rebuttal, par 5).

17. Dr. Adkins states that "[t]he assessment and informed consent process that we utilize at the Duke Gender Care Clinic is comparable to the processes used at gender clinics across the country" (Adkins rebuttal, par 6). The only way to have some certainty about that particular claim for Oklahoma is to be provided medical record evidence that the plaintiffs or other Oklahomans have followed a similar informed consent process (based on clinician progress notes and consent forms if

available) and medical record evidence of the assessments. Since that has not occurred, Dr. Adkins' claim is baseless with respect to the youth of Oklahoma.

18. Dr. Turban implies that I have misrepresented what is happening internationally and have discussed an "international consensus" (Turban rebuttal, par 6). I have never claimed that there is an international consensus, rather the opposite. There is no international consensus on the proper care for gender dysphoric youth. Let's examine more closely what has just recently occurred within NHS England for example.

19. On June 8, 2023, NHS England issued interim guidance for their specialty service for children and young people with gender dysphoria (NHS England, 2023). They wrote, "The *primary intervention for children and young people who are assessed as suitable for The Service is psychosocial (*including psychoeducation) and psychological support and intervention; the main objective is to alleviate distress associated with gender incongruence and promote the individual's global functioning and wellbeing (NHS England, section 5) (emphasis mine). They clearly do not follow the GAT model espoused by WPATH, the Endocrine Society or the plaintiffs' experts. Neither WPATH's name nor the Endocrine Society's name is mentioned within the NHS document.

20. Furthermore, NHS England has a provision for the child or young person who has started puberty blocking medications outside of NHS protocols that involves stopping the blockers for a period of time to "allow baseline investigations to be undertaken by The Service." (NHS England, p. 17) If a patient is then considered appropriate to be restarted on treatment, then blockers must be resumed under a strict protocol including "the requirement for the patient to be enrolled in the formal research protocol." (Id.) The fact that NHS England has required this subgroup of patients to be involved in a "formal research protocol" is another piece of evidence that puberty blocking medication for the treatment of gender dysphoria remains experimental.

21. I do not mean to imply that I am in full agreement with NHS England's research plans (which to my knowledge have yet to be published). Rather, I will state clearly that I do not believe that children and adolescents who are at the earliest stages of pubertal development (Tanner stage 2 or 3) nor their parents can consent or assent to future infertility and potential sterility as part of GAT even within a research protocol. But my disagreement with NHS England on this point does not somehow transform their approach into one matching that of the plaintiffs' experts. What is happening in various parts of Europe is vastly different than what plaintiffs are promoting.

22. Also significant in the discussion about Europe is a recent letter published in the Wall Street Journal, signed by 21 clinicians and researchers from nine different countries around the world.

They state that the "claim that gender transition reduces suicides is contradicted by every systematic review, including the review published by the Endocrine Society, which states, 'We could not draw any conclusions about death by suicide.' There is no reliable evidence to suggest that hormonal transition is an effective suicide-prevention measure." (Kaltiala et al., 2023). They also state that "more and more European countries and international professional organizations now recommend psychotherapy rather than hormones and surgeries as the first line of treatment for gender-dysphoric youth." (Id.)

23. In my declaration I provided examples with figures showing the exceedingly high doses of testosterone recommended for natal females and estrogen for natal males recommended by the Endocrine Society for GAT.[1] Dr. Adkins makes the unscientific and illogical claim that "[t]he guidelines recommend that the hormone levels be kept in the normal physiologic range for their gender identity, not their sex assigned at birth. The levels are thus in the physiologic range for their gender identity." (Adkins rebuttal, par 23). Gender identity, as I have described, is a purely psychological concept. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR) states that "sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and non-ambiguous internal and external genitalia" (DSM-5 TR, emphasis added). Note that gender identity is not a component of physical sex as defined by the DSM 5.

24. Gender identity in the DSM 5 is defined separately: "Gender identity is a category of social identity and refers to an individual's identification as male, female, or, occasionally, some category other than male or female" (DSM 5-TR). So, we can see that gender identity is not a physical substance but is described rather as a social identity and is a psychological (and therefore non-material) concept. A psychosocial identity has no relation to a "physiologic range" as Dr. Adkins claims. Physiologic ranges apply only to physical molecules and substances which are measured objectively in a laboratory such as testosterone, estrogen, red blood cell counts, and creatinine to provide a few examples. Furthermore, the normal physiologic ranges for these items are based on biological sex (a physical property of human beings) and not gender identity (a psychological concept describing an internal feeling).

[1] See Laidlaw declaration sections II.C.1.a. and II.C.2.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct.

Executed August 8, 2023.

Michael K. Laidlaw, M.D.

References

Caruso JP, Sheehan JP. Psychosurgery, ethics, and media: a history of Walter Freeman and the lobotomy. Neurosurg Focus. 2017 Sep;43(3):E6. doi: 10.3171/2017.6.FOCUS17257. PMID: 28859561.

Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297. PMID: 36652355; PMCID: PMC10081536.

Coleman E, et al. "Standards of Care for the Health of Transgender and Gender Diverse People, Version 8". International Journal of Transgender Health. 06 Sep 2022. International Journal of Transgender Health. https://doi.org/10.1080/26895269.2022.2100644 https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

Dhejne C, Lichtenstein P, Boman M, Johansson AL, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One. 2011 Feb 22;6(2):e16885. doi: 10.1371/journal.pone.0016885. PMID: 21364939; PMCID: PMC3043071.

Kaltiala R, et al. "Youth Gender Transition Is Pushed Without Evidence: Psychotherapy, not hormones and surgery, is increasingly the first line of treatment abroad." The Wall Street Journal. Jul 13, 2023.

NIH RePORTER. reporter.nih.gov. https://reporter.nih.gov/search/-EEMdHiQ8kyTvxzLPBxGyQ/project-details/10615754 accessed 06/20/23.

NHS England. INTERIM SERVICE SPECIFICATION Interim Specialist Service for Children and Young People with Gender Incongruence. NHS England. June 8, 2023.

Olson-Kennedy J, Chan Y, Garofalo R, Spack N, Chen D, Clark L, Ehrensaft D, Hidalgo M, Tishelman A, Rosenthal S Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study JMIR Res Protoc 2019;8(7):e14434 URL: https://www.researchprotocols.org/2019/7/e14434/PDF

Attachment 1

Children's Hospital Los Angeles

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

TRANS YOUTH CARE – BLOCKER COHORT

Subject's Name:			
Medical Record Number:		Birth Date:	

1. Dr. Olson is doing a research study about medication that can be used to stop you from going into puberty.

2. We are asking you to take part in this research because we want to learn more about what happens to children who are transgender and use a medicine to stop puberty. We want to see if it changes how your body works and want to know how you and your parents feel about not going into puberty.

3. If you agree to be in this study, you will be asked to:
   - Answer questions at the start of the research and 6 months, 1 year, 1½ years, and 2 years from now.
     - If you have not had your puberty blocker put in within 3 months of taking the first survey, you will be asked to retake the first survey.
     - The questions will take about 2 hours to complete each time and will include:
       - how you feel about your body,
       - if you feel sad or happy,
       - other types of feelings that you are having.
   - Let your doctor and some of the people who work with her look at and write down medical information about you.

4. We will also ask your parent/legal guardian to answer questions about you and about how they feel.

When you are in a research study, sometimes good things and bad things can happen:

5. Things that happen to children in research studies that make them feel bad are called "risks." Some of the bad things for this research study could be:
   - You might not like some of the questions we ask you. If you don't like a question, you do not have to answer it or you can tell us you want to stop and don't want to answer any more questions.
   - We are very careful with the answers and information you give us so that people won't see it if they're not supposed to, but sometimes they might accidentally find out something.

   Not all of these things may happen to you. None of them may happen. Or things may happen that the doctors don't know about yet.

6. Things that happen to children in research studies that are good are called "benefits." Some of the good things for this research study could be we could learn more about how this medicine affects children and how best to take care of transgender children in the future.

7. We will do everything possible to keep your information private.

8. Your parent will receive payment for each study visit.

9. You do not have to be in this study if you don't want to. You may stop being in this study at any time. Remember, being in this study is up to you.

10. Please talk with your parents before you decide whether or not to be in this study. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes," **you** can still decide not to do this.

11. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, please write it down to help you remember. You can call me or ask me next time you see me.

323-361-3128

12. Signing your name at the bottom means that you agree to be in this study. Your doctors will still take good care of you whether or not you agree to be in this study.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please put a check to mark your decision

_____Yes _____No

Yes, I agree to be in this research study.

_____ _____
Signature of Subject Date

_____
Print Name of Individual Obtaining Assent

_____ _____
Signature of Individual Obtaining Assent Date

Routing of signed copies of the assent form:
1) Give to the child (copy)
2) Give to the parent/legal guardian (copy)
3) Place in the Investigator's research files (original)

Children's Hospital Los Angeles

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care – Blocker Cohort

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

You are invited to participate in a research study conducted by Johanna Olson-Kennedy, MD, from the Division of Adolescent and Young Adult Medicine at Children's Hospital Los Angeles (CHLA). This research is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. Participation in this study is completely voluntary.

The purpose of the study is to evaluate how taking a medication called gonadotropin releasing hormone (GnRH) agonists used for blocking puberty affects your body. We will do this by looking at information about your bone health and lab results. The study also wants to understand the effects of preventing puberty on your and your parent's or legal guardian's mental health and psychological well-being. There will be a total of 110 youth participating in this study, along with one parent/legal guardian for each youth, at 4 sites across the United States.

If you volunteer to participate in this study, your participation will last 2 years and involve:

- For you:
  - Taking a survey on a computer at the start of the research and 6 months, 1 year, 1½ years, and 2 years after your puberty blocker is put in. The surveys include questions about your gender identity, how you feel about your body, depression, and other mental health issues. The surveys will take about 2 hours to complete each time.
  - If you have not had your puberty blocker put in within 3 months of taking the first survey, you will be asked to retake the first survey.
  - Allowing the research team to collect information from your medical records such as your height and weight, blood pressure, lab results, bone health, medications you take, and diagnoses.
- For your parent/legal guardian:
  - Completing a computer based survey about your child at the start of the research and 6 months, 1 year, 1½ years, and 2 years after your child's puberty blocker is put in. These surveys include questions about your child's gender identity and quality of life. Additionally you will be asked about your experience as a caregiver of a gender non-conforming child. The surveys will take about 2 hours to complete each time.
  - Participating in an interview or additional questionnaires about your child's behaviors and physical and mental health at the start of the research and 1 year and 2 years after

[1] This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

your child's puberty blocker is put in. These interviews will take from 1 hour to 2 hours.

It is possible that some questions in the survey may make you feel uncomfortable. If you do not feel comfortable answering a question, you can choose not to answer that question or you can stop filling out the questionnaire. There is the potential of accidental release of confidential information. To protect against this risk, your name and any other personal identifying information will not be shared with anyone else. We will use a secret code on your surveys and forms, and the list that links your name and the secret code is kept in a password-protected file on the CHLA computer network. There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

You should not expect any direct benefit as a result of participating in this research; however, the information that we learn from this research can help us improve care for transgender youth in the future. The alternative to participation is to not participate.

In consideration for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows: $50 for each visit; if you participate in all visits, the total amount is $400.

If the payments are greater than $150 per visit or if there is a possibility that you could receive $600 or more for your participation in any Children's Hospital Los Angeles studies, you will need to provide the name, address, date of birth, and social security number (or taxpayer ID number) of the person (family or friend) you'd like to receive the payments. If payments (for all research and/or clinical programs) in a calendar year equal $600 or more, the income will be reported to the IRS and a 1099 form will be issued. The person you designate to receive the payments can use this form with their income tax return, if appropriate.

In addition to payments, and in consideration of the expenses you may have related to participation in the research, you or a family member or friend you designate will receive reimbursement for parking and/or transportation or be provided transportation, as needed. To receive reimbursements, you will need to provide a name and date of birth. For each expense, you will also need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

To receive either payments or reimbursements (or both), you will be issued a ClinCard, which is a specially designed debit card for clinical research. When a visit is completed, funds will be approved and loaded onto your card and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, please ask the research coordinator for a replacement ClinCard. If the ClinCard funds are not used within 6 months, a fee will be deducted. You will be provided details about the use of the ClinCard in a separate form.

All personal information collected for payments or reimbursement is stored in a secure fashion and will be kept completely confidential.

If you don't wish to receive payment or reimbursement (or both), you have other choices. You can decline payment and/or reimbursement or you can choose to donate the funds set aside for your participation to Children's Hospital Los Angeles (a non-profit hospital), to be used in the area of greatest need or for a specific program you can designate.

Please let the research team know how you would like to manage the funds set aside for your participation.

This study includes procedures that are also a part of standard treatment. The cost of these procedures will be billed to your insurance or other third-party payer. Your family may be responsible for any co-pays or deductibles.

Only the research team will know that you are a research subject and have access to the information you provide. You will not be identified in publications of the research results. Authorized representatives of the Department of Health and Human Services and the CHLA Institutional Review Board may review subject records but are bound by rules of confidentiality not to reveal your identity. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Your choice about whether or not to participate will have no effect on your care, services or benefits at Children's Hospital Los Angeles. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at CHLA.

You may be removed from the study by the investigator to protect your health or if other situations arise that make it necessary to do so. If you experience certain side effects such as depression, anxiety, or emotional distress because of your participation, you may have to drop out even if you would like to continue. The investigator, Dr. Olson-Kennedy, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If there is significant new information found during the course of the study or the research plan is changed in a way that might affect your decision to continue participating in the study, you will be informed and your consent to continue participating in the study may be requested.

If you have questions about the research or wish to report a concern or complaint about the research, the Principal Investigator, Dr. Olson, may be reached at 323-361-3128. You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call the CHLA Human Subjects Protection Program at 323-361-2265.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please provide your **initials** beside your decision.

_____Yes _____No [for subject to complete, if the subject is 14 years or older]

_____Yes _____No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

_____ _____

Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____

Signature of Parent/Legal Guardian Date

_____ _____

Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____

Print Name of Individual Obtaining Consent

_____ _____

Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

Routing of signed copies of the form:

1) Give to the subject if at least 14 years old (copy)
2) Give to the parent/legal guardian if subject is a minor (copy)
3) Place in the Principal Investigator's research file (original)

Children's Hospital Los Angeles

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Addendum to Consent Form for
The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

You are currently enrolled in a research study at Children's Hospital Los Angeles. When you began the study you were under the age of 18 years and your parent or legal guardian gave their permission for you to participate. Now that you are an adult, you have the legal right to consent for your own continued participation.

The original consent form for the study is attached. A member of the research team will discuss the remaining study activities with you. Participation in this study is completely voluntary. Please read the information provided, and ask questions about anything you do not understand, before deciding whether or not to participate.

SIGNATURE OF RESEARCH SUBJECT

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to your participation in this research study; and
- You will be given a signed copy of this.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and have answered all of his/her questions. I believe that he/she understands all of the information described in this document and freely gives consent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

Routing of signed copies of the consent form:

1) Give to the subject (copy)
2) Place in the Principal Investigator's research file (original)

Children's Hospital Los Angeles

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

TRANS YOUTH CARE – GENDER-AFFIRMING HORMONE COHORT

Subject's Name:			
Medical Record Number:		Birth Date:	

1. Dr. Olson-Kennedy is doing a research study about how using gender-affirming hormones for gender transition affect children and adolescents.

2. We are asking you to take part in this research because we want to learn more about what happens to children and adolescents who are transgender and use gender-affirming hormones for gender transition. We want to see if it changes how your body works and want to know how you feel about transitioning your body to match your gender.

3. If you agree to be in this study, you will be asked to:
   - Answer questions at the start of the research, and 6 months, 1 year, 1½ years, and 2 years after you start gender-affirming hormones.
     - If you have not started gender-affirming hormones within 3 months of taking the first survey – at the start of the research – you will be asked to retake the first survey.
     - The questions will take about 2 hours to complete each time and will include:
       - how you feel about your body
       - if you feel sad or happy
       - drug and alcohol use
       - your physical activity and types of food you eat
       - other types of feelings that you are having
     - At your last study visit, we will also ask you about how it felt being in the study and what you thought about some of the questions we asked you.

- Let your doctor and some of the people who work with them look at and write down medical information about you.

When you are in a research study, sometimes good things and bad things can happen:

4. Things that happen to children in research studies that make them feel bad are called "risks." Some of the bad things for this research study could be:
   - You might not like some of the questions we ask you. If you don't like a question, you do not have to answer it or you can tell us you want to stop and don't want to answer any more questions.
   - We are very careful with the answers and information you give us so that people won't see it if they're not supposed to, but sometimes they might accidentally find out something.

   Not all of these things may happen to you. None of them may happen. Or things may happen that the doctors don't know about yet.

5. Things that happen to children in research studies that are good are called "benefits." Some of the good things for this research study could be we could learn more about how this medicine affects children and how best to take care of transgender children in the future.

6. We will do everything possible to keep your information private.

7. You do not have to be in this study if you don't want to. You may stop being in this study at any time. Remember, being in this study is up to you.

8. Your parent will receive payment for each study visit.

9. Please talk with your parent/legal guardian before you decide whether or not to be in this study. We will also ask your parent/legal guardian to give their permission for you to take part in this study. But even if your parent/legal guardian say "yes," **you** can still decide not to do this.

10. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, please write it down to help you remember. You can call me or ask me next time you see me.

323-361-3128

11. Signing your name at the bottom means that you agree to be in this study. Your doctors will still take good care of you whether or not you agree to be in this study.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please put a check to mark your decision

_____Yes _____No

Yes, I agree to be in this research study.

_____ _____

Signature of Subject Date

_____

Print Name of Individual Obtaining Assent

_____ _____

Signature of Individual Obtaining Assent Date

Routing of signed copies of the assent form:

1) Give to the child (copy)
2) Give to the parent/legal guardian (copy)
3) Place in the Investigator's research files (original)

Children's Hospital Los Angeles

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care – Gender-Affirming Hormone Cohort

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

You are invited to participate in a research study conducted by Johanna Olson-Kennedy, MD, from the Division of Adolescent and Young Adult Medicine at Children's Hospital Los Angeles (CHLA). This research is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. Participation in this study is completely voluntary.

The purpose of the study is to evaluate how using gender-affirming hormones for gender transition affect your body by looking at your lab results, vital signs, and body changes, such as how your liver is working, what your blood sugar level is, and what your blood pressure is. The study also wants to understand the effects of using gender-affirming hormones for gender transition on your mental health and psychological well-being. There will be a total of 350 youth participating in this study at 4 sites across the United States.

If you volunteer to participate in this study, your participation will last 2 years and involve:

- Taking a survey on a computer at the start of the research and 6 months, 1 year, 1½ years, and 2 years after you start gender-affirming hormones. The surveys include questions about your gender identity, your gender-affirming care, your physical activity, what types of food you eat, how you feel about your body, depression, drug and alcohol use, and other mental health issues. The last survey will include questions about how you felt about being in the study and what you thought about some of the questions you were asked. The surveys will take about 2 hours to complete each time.
- Participating in an interview or additional questionnaires about your behaviors and physical and mental health at the start of the research, 1 year, and 2 years after you start gender-affirming hormones. These interviews or questionnaires will take from 1 to 2 hours.
- If you have not started gender-affirming hormones within 3 months of taking the first survey – at the start of the research – you will be asked to retake the first survey.
- Allowing the research team to collect information from you or your medical records such as your height and weight, blood pressure, lab results, medications you take, diagnoses, and body changes from starting gender-affirming hormones.

[1] This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

It is possible that some questions in the survey may make you feel uncomfortable. If you do not feel comfortable answering a question, you can choose not to answer that question or you can stop filling out the questionnaire. There is the potential of accidental release of confidential information. To protect against this risk, your name and any other personal identifying information will not be shared with anyone else. We will use a secret code on your surveys and forms, and the list that links your name and the secret code is kept in a password-protected file on the CHLA computer network. There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

You should not expect any direct benefit as a result of participating in this research; however, the information that we learn from this research can help us improve care for transgender youth in the future. The alternative to participation is to not participate.

In consideration for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows: $50 for each visit; if you participate in all visits, the total amount is $400.

If the payments are greater than $150 per visit or if there is a possibility that you could receive $600 or more for your participation in any Children's Hospital Los Angeles studies, you will need to provide the name, address, date of birth, and social security number (or taxpayer ID number) of the person (family or friend) you'd like to receive the payments. If payments (for all research and/or clinical programs) in a calendar year equal $600 or more, the income will be reported to the IRS and a 1099 form will be issued. The person you designate to receive the payments can use this form with their income tax return, if appropriate.

In addition to payments, and in consideration of the expenses you may have related to participation in the research, you or a family member or friend you designate will receive reimbursement for parking and/or transportation or be provided transportation, as needed. To receive reimbursements, you will need to provide a name and date of birth. For each expense, you will also need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

To receive either payments or reimbursements (or both), you will be issued a ClinCard, which is a specially designed debit card for clinical research. When a visit is completed, funds will be approved and loaded onto your card and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, please ask the research coordinator for a replacement ClinCard. If the ClinCard funds are not used within 6 months, a fee will be deducted. You will be provided details about the use of the ClinCard in a separate form.

All personal information collected for payments or reimbursement is stored in a secure fashion and will be kept completely confidential.

If you don't wish to receive payment or reimbursement (or both), you have other choices. You can decline payment and/or reimbursement or you can choose to donate the funds set aside for your participation to Children's Hospital Los Angeles (a non-profit hospital), to be used in the area of greatest need or for a specific program you can designate.

Please let the research team know how you would like to manage the funds set aside for your participation.

This study includes procedures that are also a part of standard treatment. The cost of these procedures will be billed to your insurance or other third-party payer. Your family may be responsible for any co-pays or deductibles.

Only the research team will know that you are a research subject and have access to the information you provide. You will not be identified in publications of the research results. Authorized representatives of the Department of Health and Human Services and the CHLA Institutional Review Board may review subject records but are bound by rules of confidentiality not to reveal your identity. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Your choice about whether or not to participate will have no effect on your care, services or benefits at Children's Hospital Los Angeles. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at CHLA.

You may be removed from the study by the investigator to protect your health or if other situations arise that make it necessary to do so. If you experience certain side effects such as depression, anxiety, or emotional distress because of your participation, you may have to drop out even if you would like to continue. The investigator, Dr. Olson-Kennedy, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If there is significant new information found during the course of the study or the research plan is changed in a way that might affect your decision to continue participating in the study, you will be informed and your consent to continue participating in the study may be requested.

If you have questions about the research or wish to report a concern or complaint about the research, the Principal Investigator, Dr. Olson-Kennedy, may be reached at 323-361-3128. You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call the CHLA Human Subjects Protection Program at 323-361-2265.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please provide your initials beside your decision.

_____Yes _____No [for subject to complete, if the subject is 14 years or older]

_____Yes _____No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study; and
- You will be given a signed copy of this form.

_____ _____
Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____
Signature of Parent/Legal Guardian Date

_____ _____
Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

Routing of signed copies of the form:

1) Give to the subject if at least 14 years old (copy)
2) Give to the parent/legal guardian if subject is a minor (copy)
3) Place in the Principal Investigator's research file (original)

Children's Hospital Los Angeles

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth

Trans Youth Care – Gender-Affirming Hormone Cohort

Addendum: New Information

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

You were previously informed that if there was significant new information found during the course of the study or the research plan was changed in a way that might affect your decision to continue participating in the study, you would be informed and your consent to continue participating in the study could be requested.

The research plan for the study in which you are currently participating at Children's Hospital Los Angeles has changed.

The research study team would like to ask you some questions about how you felt being in the research study and how you felt answering some of the questions in the computer survey.

You have the right to withdraw from this research study at any time and discontinue participation without penalty. Your choice about whether or not to continue participating will have no effect on your care, services or benefits at Children's Hospital Los Angeles.

The original consent form for the study is attached. A member of the research team will discuss the new information with you. Continued participation in this study is completely voluntary. Please read the information provided and ask questions about anything you do not understand, before deciding whether or not to continue participating in the research.

If after receiving this information you agree to continue taking part in this research study, please sign below.

[1] This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study; and
- You will be given a signed copy of this form.

_____ _____
Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____
Signature of Parent/Legal Guardian Date

_____ _____
Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

My signature as Witness indicates that the subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed this consent/permission/assent form addendum in my presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INTERPRETER (if applicable)

_____
Print Name of Interpreter

_____ _____
Signature of Interpreter Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

Please check appropriate box and sign below.

☐ The undersigned, _____, hereby certifies that verbal assent was obtained from the subject.

☐ Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information.)

_____

_____

Date:_____

Time:_____ Signature_____

Routing of signed copies of the form:
1) Give to the subject (copy)
2) Give to the parent/legal guardian if subject is a minor (copy)
3) Place in the Principal Investigator's research file (original)

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Feminizing Medications (transfeminine individuals on GnRH analogs)

This form refers to the use of estrogen by persons in the male-to-female spectrum who wish to become feminized to reduce gender dysphoria and facilitate a more feminine gender presentation. While there are risks associated with taking feminizing medications, when appropriately prescribed they can greatly improve mental health and quality of life.

This form covers the known and unknown benefits, risks, and changes that may occur from taking feminizing medication. If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

1. Estrogen is being prescribed to reduce male physical features and feminize the body.

2. The feminizing effects of estrogen can take several months or longer to become noticeable, and that the rate and degree of change can't be predicted.

3. If you are taking estrogen you will probably develop breasts, and:

- Although most breast development occurs over the first two years of starting hormones, they may take several years to develop to their full size.
- Even if estrogen is stopped, the breast tissue that has developed will remain.
- There may be milky nipple discharge (galactorrhea). This can be caused by taking estrogen or by an underlying medical condition. It is advised to check with a doctor to determine the cause.
- Reported cases of breast cancer in transgender women are extraordinarily rare, and only 10 cases have been reported in the literature as of 2016.

4. The following changes are generally not permanent (that is, they will likely reverse if I stop taking feminizing medications):

- Skin may become softer.
- Fat may redistribute to a more feminine pattern (decreased in abdomen, increased on buttocks/hips/thighs – changing from "apple shape" to "pear shape").

5. Taking feminizing medications after or while being on GnRH analogs will likely lead to infertility, particularly when GnRH analogs have been started in early puberty.

- Sperm will not mature, leading to infertility. The ability to make sperm normally may or may not come back even after stopping taking feminizing medication.
- The amount of fluid ejaculated may be reduced.
- There is typically a decrease in morning and spontaneous erections.
- Erections may not be firm enough for penetrative sex.

• Libido (sex drive) may decrease.

Risks of Feminizing Medications

The medical effects and safety of feminizing medications in youth younger than age 18 are not fully understood, there may be long-term risks that are not yet known. You are strongly advised not to take more medication than prescribed, as this increases health risks. Taking more than prescribed will not make feminization happen more quickly or increase the degree of change. Also, extra estrogen can be converted to testosterone, which may slow or stop feminization.

6. Estrogen minimally increases the risk of blood clots, which can result in:

- pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- stroke, which may cause permanent brain damage or death
- heart attack
- chronic leg vein problems

If you experience any of the following symptoms, you should call 911, or go to the emergency room:

- Unexplained shortness of breath
- Rapid breathing
- Chest pain
- Rapid heart rate
- Light headedness or passing out
- Leg pain or tenderness, especially in the calf
- Leg swelling

The risk of blood clots is worse if you smoke cigarettes. Please be advised that you should stop smoking completely if you start taking estrogen.

7. Estrogen can occasionally result in the following physiologic changes:

- increase deposits of fat around my internal organs, which is associated with increased risk for diabetes and heart disease.
- increased blood pressure
- increased risk of gallstones
- nausea and vomiting, similar to morning sickness in pregnant women
- headaches or migraines

8. In very rare instances, estrogen increases the risk of non-cancerous tumors of the pituitary gland (prolactinoma). Although prolactinomas are typically not life-threatening, it can damage vision and cause headaches. Your prolactin will be checked when you first start taking estrogen.

9. Dangerous side effects from estrogen are greater in those who: smoke, are overweight, have a history of blood clots or high blood pressure.

Feminizing medications will result in changes that will be noticeable by other people, and some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Please be advised that referrals can be made for support/counseling if this would be helpful.

Some people experience changes in their mood when taking estrogen. We strongly encourage youth to establish or continue in mental health therapy for support of this change, and other challenges that may arise as a result of physical gender transition.

Preventing Medical Complications

Taking feminizing medications as prescribed and letting your health care provider know if you are not happy with the treatment or are experiencing any problems helps prevent potential complications.

The right dose or type of medication prescribed for you may not be the same as for someone else, so it's best not to compare to others also undergoing physical gender transition.

Physical examinations and blood tests are needed on a regular basis to check for negative side effects of feminizing medications.

Some medical conditions make it dangerous to take estrogen. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.

You can choose to stop taking feminizing medication at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

My signature below confirms that:

- My doctor has talked with me about the benefits and risks of feminizing medication, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- I understand the risks that may be involved.
- I understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- I have had sufficient opportunity to discuss treatment options with my doctor. All of my questions have been answered to my satisfaction.

_____ _____
Patient Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Provider Signature Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Feminizing Medications

This form refers to the use of estrogen and/or androgen antagonists (sometimes called “anti-androgens” or “testosterone blockers”) by persons in the male-to-female spectrum who wish to become feminized to reduce gender dysphoria and facilitate a more feminine gender presentation. While there are risks associated with taking feminizing medications, when appropriately prescribed they can greatly improve mental health and quality of life.

This form covers the known and unknown benefits, risks, and changes that may occur from taking feminizing medication. If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

Feminizing Effects

1. Estrogen, androgen antagonists, or a combination of the two may be prescribed to reduce male physical features and feminize the body.

2. The feminizing effects of estrogen and androgen antagonists can take several months or longer to become noticeable, and that the rate and degree of change can’t be predicted.

3. If you are taking estrogen you will probably develop breasts, and:

- Although most breast development occurs over the first two years of starting hormones, they may take several years to develop to their full size.
- Even if estrogen is stopped, the breast tissue that has developed will remain.
- There may be milky nipple discharge (galactorrhea). This can be caused by taking estrogen or by an underlying medical condition. It is advised to check with a doctor to determine the cause.
- Reported cases of breast cancer in transgender women are extraordinarily rare, and only 10 cases have been reported in the literature as of 2016.

4. The following changes are generally not permanent (that is, they will likely reverse if I stop taking feminizing medications):

- Skin may become softer.
- Muscle mass decreases and there may be a decrease in upper body strength.
- Body hair growth may become less noticeable and grow more slowly, but it will likely not stop completely even after years on medication.
- Male pattern baldness may slow down, but will probably not stop completely, and hair that has already been lost will likely not grow back.
- Fat may redistribute to a more feminine pattern (decreased in abdomen, increased on buttocks/hips/thighs – changing from “apple shape” to “pear shape”).

5. Feminizing medications will make the testicles produce less testosterone, which can affect overall sexual function:

- Sperm may not mature, leading to reduced fertility. The ability to make sperm normally may or may not come back even after stopping taking feminizing medication. The options for sperm banking have been explained. People taking estrogen may still be able to make someone pregnant.
- Testicles may shrink by 25-50%. Regular testicular examinations are still recommended.
- The amount of fluid ejaculated may be reduced.
- There is typically a decrease in morning and spontaneous erections.
- Erections may not be firm enough for penetrative sex.
- Libido (sex drive) may decrease.

6. Some aspects of body are not significantly changed by feminizing medications:

- Beard/moustache hair may grow more slowly and be less noticeable, but will not go away.
- Voice pitch will not rise and speech patterns will not become more feminine.
- The laryngeal prominence (“Adam’s apple”) will not shrink.

Although feminizing medication does not change these features, there are other treatments that may be helpful. If there are any concerns about these issues, referrals can be provided to help explore treatment options.

Risks of Feminizing Medications

The medical effects and safety of feminizing medications in youth younger than age 18 are not fully understood, and that there may be long-term risks that are not yet known. You are strongly advised not to take more medication than prescribed, as this increases health risks. Taking more than prescribed will not make feminization happen more quickly or increase the degree of change. Also, extra estrogen can be converted to testosterone, which may slow or stop feminization.

7. Estrogen minimally increases the risk of blood clots, which can result in:

- pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- stroke, which may cause permanent brain damage or death
- heart attack
- chronic leg vein problems

If you experience any of the following symptoms, you should call 911, or go to the emergency room:

- Unexplained shortness of breath
- Rapid breathing
- Chest pain
- Rapid heart rate
- Light headedness or passing out
- Leg pain or tenderness, especially in the calf
- Leg swelling

The risk of blood clots is worse if you smoke cigarettes. Please be advised that you should stop smoking completely if you start taking estrogen.

8. Estrogen can occasionally result in the following physiologic changes:

- increase deposits of fat around my internal organs, which is associated with increased risk for diabetes and heart disease.
- increased blood pressure
- increased risk of gallstones
- nausea and vomiting, similar to morning sickness in pregnant women
- headaches or migraines

9. In very rare instances, estrogen increases the risk of non-cancerous tumors of the pituitary gland (prolactinoma). Although prolactinomas are typically not life-threatening, it can damage vision and cause headaches. Your prolactin will be checked when you first start taking estrogen.

10. Dangerous side effects from estrogen are greater in those who: smoke, are overweight, have a history of blood clots or high blood pressure.

Feminizing medications will result in changes that will be noticeable by other people, and that some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Please be advised that referrals can be made for support/counseling if this would be helpful.

Some people experience changes in their mood when taking estrogen. We strongly encourage youth to establish or continue in mental health therapy for support of this change, and other challenges that may arise as a result of physical gender transition.

Risks Associated with Androgen Antagonists

Spironolactone affects the balance of water and salts in the kidneys, and that this may:

- increase the amount of urine produced, making it necessary to urinate more frequently
- reduce blood pressure
- increase thirst
- rarely, cause high levels of potassium in the blood, which can cause changes to heart rhythm that may be life-threatening

Preventing Medical Complications

Taking feminizing medications as prescribed and letting your health care provider know if you are not happy with the treatment or are experiencing any problems helps prevent potential complications.

The right dose or type of medication prescribed for you may not be the same as for someone else, so it’s best not to compare to others also undergoing physical gender transition.

Physical examinations and blood tests are needed on a regular basis to check for negative side effects of feminizing medications.

Some medical conditions make it dangerous to take estrogen. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.

You can choose to stop taking feminizing medication at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

My signature below confirms that:

- My doctor has talked with me about the benefits and risks of feminizing medication, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- I understand the risks that may be involved.
- I understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- I have had sufficient opportunity to discuss treatment options with my doctor. All of my questions have been answered to my satisfaction.

_____ _____
Patient Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Provider Signature Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

PUBERTAL BLOCKERS FOR MINORS IN EARLY ADOLESCENCE

Parent or Guardian Consent

Before initiating a medication for your child to put puberty "on hold", there are several things you need to know. There are possible advantages, disadvantages and risks with pubertal blockers. It's important that you understand all of this information before your child begins the medication.

Please read the following carefully and ask us any questions. We want you to be very comfortable and sure of what pubertal blockers offer your child.

After your questions and concerns are addressed and you have decided to proceed with the pubertal blocker medication for your child, both of you will need to sign this information and consent form.

What are the different medications that can help to stop the physical changes of puberty?

The main way that the physical changes of puberty can be put on hold is by blocking the signal from the brain to the organs that make the hormones of puberty. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

The medications are called Pubertal Blockers. They are also known as a class of medication called GnRH analogues. These medications are given monthly, once every three months, or in the form of an implant that is placed in the upper arm, and stays in for 12-24 months. This medication is effective for both males and females. They can be started just after the early physical changes of puberty.

For transgender girls there are alternative medicines that can block the effect of testosterone. The most common medication of this type is called spironolactone. There is a separate consent form for this medication. Spironolactone is not as effective at blocking puberty in transgender girls, but it is much less expensive.

Every medication has risks, benefits, and side effects that are important to understand before starting. It is also important to know how they work.

Medications for Blocking Puberty

- Puberty Blockers are used to help temporarily suspend or block the physical changes of puberty for your child.

- It can take several months for the medication to be effective. While no one can predict how quickly or slowly your child's body will respond, most youth respond within 3-4 weeks of initiating blockers.

- This medication is not specifically made for the purpose of blocking puberty (they are not FDA approved for this purpose) in transgender youth, however pediatric endocrinologists (children's doctors who work with hormones and puberty), recommend these medications if the physical changes of puberty need to be postponed. They have been in use for this purpose for more than 30 years.

- The medication is not permanent. If your child stops getting the injections, or has the implant removed, in about six months their body will restart the changes of puberty at the developmental stage they were at when they started the hormone blocker.

- By taking these medications, your child's body will not be making the hormones of puberty, testosterone or estrogen.

- Providing these medicines to your child may assist in avoiding the unhappiness and trauma of unwanted puberty, giving your child the opportunity to develop in their affirmed gender, with a better fit between body and psyche. It may also help them avoid the need for surgeries and other treatments (i.e. mastectomies for transmen, tracheal shaving or electrolysis for transwomen) that would be required to try to reverse the effects of puberty.

- If you are interested in getting more information about puberty suppression, we can refer you to an endocrinologist.

- We recommend that your child and family participate in therapy with a therapist experienced in gender issues while your child is taking the hormone blocker.

Risks of Puberty Blockers

- The side effects and the safety of these medicines are not completely understood. There may be long-term risks that are not yet known.

- If your child starts puberty blockers in the earliest stages of puberty, and then goes on to gender affirming hormones, they will not develop sperm or eggs. This means that they will not be able to have biological children. *This is an important aspect of blocking puberty and progressing to hormones that you should understand prior to moving forward with puberty suppression.* If your child discontinues the use of blockers, and does not go on gender affirming hormones, they will continue their pubertal development about 6-12 months after stopping the medication, and fertility would be maintained.

- While on puberty blockers, your child's bone density will go back to developing at a pre-pubertal rate. While the clinical impact of this is not yet known, we will obtain bone density

scans at the beginning of puberty suppression, and each year thereafter to monitor your child's bone density.

- It's possible that your child will get taller while on these medications. This can be problematic for transgender girls to achieve a typical female height. In transgender boys, delaying the onset of puberty may actually make him slightly taller (one of the reasons that girls are usually shorter than boys is because puberty is started earlier).

- These medicines will be stopping the development of puberty for your child and other people may notice. As your child becomes older, this may become more apparent.

- Some transgender people have experienced harassment and discrimination. You can get resources that will support your child and your family. Parents and guardians frequently have to advocate for children to participate safely and free from harassment in schools and other activities. You can ask your child's provider and therapist for help advocating for your child.

Prevention of Medical Complications

- Please take your puberty blocking medication as prescribed. Tell your health care provider if your child has any problems or side effects or is unhappy with the medication.

- Your child needs periodic check-ups to make sure that your child is responding appropriately.

- Using these medicines to block puberty is an off-label use. This means it is not approved by the Food and Drug Administration for this specific use. This medication is recommended for your child based on the judgment and experience of our health care provider and is supported by the Society of Pediatric Endocrinology.

- Your child can choose to stop taking these medications at any time. If your child decides to do that, stop the medications with the help of your health care provider.

Our signatures below confirm that

- Your child's health care provider has talked with you about the benefits and risks of puberty blockers for your child.

- The possible or likely consequences of using puberty blockers and potential alternative treatments.

- You understand the risks that may be involved.

- You know that the information in this form includes the known effects and risks. You also know that there may be unknown long-term effects or risks.

- You have had enough opportunity to discuss treatment options with your child's health care provider.

- All of your questions have been answered to your satisfaction.

- You have enough information to provide informed consent for your child to take, refuse, or postpone using puberty blocking medications.
- Your child is in agreement with this treatment and the signature of your child on this form attests to this agreement.
- Your signature attests to your consent for your child to begin the puberty suppression with GnRH analogs.

Patient Signature	Date
Parent or Guardian signature	Date
Parent or Guardian signature	Date
Prescribing clinician signature	Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Testosterone Therapy

This form refers to the use of testosterone by persons in the female-to-male spectrum who wish to become more masculine to reduce gender dysphoria and facilitate a more masculine gender presentation. While there are risks associated with taking testosterone, when appropriately prescribed it can greatly improve mental health and quality of life.

This form covers the known and unknown benefits, risks, and changes that may occur from taking masculinizing medication. If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

Masculinizing Effects

Testosterone is being prescribed to reduce female physical characteristics and masculinize your body. The masculinizing effects of testosterone can take several months or longer to become noticeable, the rate and degree of change can't be predicted, and changes may not be complete for 2-5 years after you start testosterone.

1. The following changes will likely be permanent even if you stopped taking testosterone:
    - Lower voice pitch (i.e., voice becoming deeper).
    - Increased growth of hair, with thicker/coarser hairs, on arms, legs, chest, back, and abdomen.
    - Gradual growth of moustache/beard hair.
    - Hair loss at the temples and crown of the head, with the possibility of becoming completely bald.
    - Genital changes may or may not be permanent if testosterone is stopped early. These include clitoral growth (typically 1-3 cm) and vaginal dryness.

2. The following changes are usually not permanent (that is, they will likely reverse if you stop taking testosterone):
    - Acne, which may be severe and can cause permanent scarring if not treated.
    - Fat may redistribute to a more masculine pattern (decreased on buttocks/hips/thighs, increased in abdomen – changing from "pear shape" to "apple shape").
    - Increased muscle mass and upper body strength.
    - Increased libido (sex drive).
    - Menstrual periods typically stop within 1-6 months of starting testosterone.
3. It is not known what the effects of testosterone are on fertility. Even if you stop taking testosterone it is uncertain if you will be able to get pregnant in the future. Even after testosterone stops your menstrual periods it may still be possible for you to get pregnant, and we advise that you consider birth control options (if applicable). You cannot take testosterone if you are pregnant

4. Your chest tissue may appear slightly smaller due to fat loss, but will not substantially shrink.

Risks of Testosterone

The medical effects and safety of testosterone use in those younger than 18 are not fully understood, and there may be long-term risks that are not yet known.

You are strongly advised not to take more testosterone than prescribed, as this increases health risks. Taking more than prescribed will not make masculinization happen more quickly or increase the degree of change: extra testosterone can be converted to estrogen, which may slow or stop masculinization.

The following are potential medical risks of testosterone:

- Increase your risk of heart disease, including:
    - decreasing good cholesterol (HDL) and increasing bad cholesterol (LDL)
    - increasing blood pressure
    - increasing deposits of fat around your internal organs

  Your risk of heart disease is greater if people in your family have had heart disease, if you are overweight, or if you smoke. Heart health checkups, including monitoring of your weight and cholesterol levels, should be done periodically as long as you are taking testosterone.

- Increase the red blood cells and hemoglobin, and while the increase is usually only to a normal male range (which does not pose health risks), a high increase can cause potentially life-threatening problems such as stroke and heart attack. Your blood should be monitored periodically while you are taking testosterone.

- Increase your risk for diabetes by decreasing your body's response to insulin, causing weight gain, and increasing deposits of fat around your internal organs. Your fasting blood glucose should be monitored periodically while you are taking testosterone.

- Lead to your cervix and the walls of your vagina becoming more fragile, and that this can lead to tears or abrasions that increase the risk of sexually transmitted infections (including HIV) if you have vaginal sex – no matter what the gender of your partner is. Frank discussion with your doctor about your sexual practices can help determine how best to prevent and monitor for sexually transmitted infections.

- Cause headaches or migraines. If you are frequently having headaches or migraines, or the pain is unusually severe, it is recommended that you talk with your health care provider.

- Testosterone can cause emotional changes, including increased irritability, frustration, and anger. We can assist you in finding resources to explore and cope with these changes if necessary.

Testosterone will result in changes that will be noticeable by other people, and some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Your care team can assist in finding advocacy and support resources.

Prevention of Medical Complications

In order to decrease potential medical complications, take testosterone as prescribed and tell your doctor if you are not happy with the treatment or are experiencing any problems.

- The right dose or type of medication prescribed for you may not be the same as for someone else.
- Physical examinations and blood tests are needed on a regular basis to check for negative side effects of testosterone.
- Some medical conditions make it dangerous to take testosterone. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.
- You can choose to stop taking testosterone at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

Your signature below confirms that:

- Your doctor has talked with you about the benefits and risks of testosterone, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- You understand the risks that may be involved.
- You understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- You have had sufficient opportunity to discuss treatment options with your doctor. All of your questions have been answered to your satisfaction.
- You believe you have adequate knowledge on which to base informed consent to the provision of testosterone therapy.

_____ _____
Patient Signature Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Provider Signature Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Testosterone Therapy (for youth on GnRH analogs)

This form refers to the use of testosterone by persons in the female-to-male spectrum who wish to become more masculine to reduce gender dysphoria and facilitate a more masculine gender presentation. While there are risks associated with taking testosterone, when appropriately prescribed it can greatly improve mental health and quality of life.

If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

Masculinizing Effects

Testosterone is being prescribed to reduce female physical characteristics and masculinize your body. The masculinizing effects of testosterone can take several months or longer to become noticeable, the rate and degree of change can't be predicted, and changes may not be complete for 2-5 years after you start testosterone.

1. The following changes will likely be permanent even if you stopped taking testosterone:
    - Lower voice pitch (i.e., voice becoming deeper).
    - Increased growth of hair, with thicker/coarser hairs, on arms, legs, chest, back, and abdomen.
    - Gradual growth of moustache/beard hair.
    - Hair loss at the temples and crown of the head, with the possibility of becoming completely bald.
    - Genital changes may or may not be permanent if testosterone is stopped. These include clitoral growth (typically 1-3 cm) and vaginal dryness.

2. The following changes are usually not permanent (that is, they will likely reverse if you stop taking testosterone):
    - Acne, which may be severe and can cause permanent scarring if not treated.
    - Fat may redistribute to a more masculine pattern (decreased on buttocks/hips/thighs, increased in abdomen – changing from "pear shape" to "apple shape").
    - Increased muscle mass and upper body strength.
    - Increased libido (sex drive).
    - Menstrual periods typically stop within 1-6 months of starting testosterone.
3. It is not known what the effects of testosterone are on fertility. If you started puberty blockers in the early stages of your puberty, then you will not have mature enough eggs to reproduce. Even if you stop taking testosterone and blockers, and progress through your puberty, it is uncertain if you will be able to get pregnant in the future. While it is unlikely that you could get pregnant while on blockers

and testosterone, we strongly recommend that you use condoms for prevention of pregnancy and transmission of sexually transmitted infections.

4. If you developed chest tissue prior to starting blockers, it may appear slightly smaller when starting testosterone due to fat loss, but will not substantially shrink.

Risks of Testosterone

The medical effects and safety of testosterone use in those younger than 18 are not fully understood, and that there may be long-term risks that are not yet known.

You are strongly advised not to take more testosterone than prescribed, as this increases health risks. Taking more than prescribed will not make masculinization happen more quickly or increase the degree of change: extra testosterone can be converted to estrogen, which may slow or stop masculinization.

The following are potential medical risks of testosterone:

- Increase your risk of heart disease, including:
    - decreasing good cholesterol (HDL) and increasing bad cholesterol (LDL)
    - increasing blood pressure
    - increasing deposits of fat around your internal organs

Your risks of heart disease are greater if people in your family have had heart disease, if you are overweight, or if you smoke. Heart health checkups, including monitoring of your weight and cholesterol levels, should be done periodically as long as you are taking testosterone.

- Cause damage to the liver, possibly leading to liver disease. Monitoring for possible liver damage as long as you are taking testosterone is advised.

- Increase the red blood cells and hemoglobin, and while the increase is usually only to a normal male range (which does not pose health risks), a high increase can cause potentially life-threatening problems such as stroke and heart attack. Your blood should be monitored periodically while you are taking testosterone.

- Increase your risk for diabetes by decreasing your body's response to insulin, causing weight gain, and increasing deposits of fat around your internal organs. Your fasting blood glucose should be monitored periodically while you are taking testosterone.

- Lead to your cervix and the walls of your vagina becoming more fragile, and that this can lead to tears or abrasions that increase the risk of sexually transmitted infections (including HIV) if you have vaginal sex – no matter what the gender of your partner is. Frank discussion with your doctor about your sexual practices can help determine how best to prevent and monitor for sexually transmitted infections.

- Cause headaches or migraines. If you are frequently having headaches or migraines, or the pain is unusually severe, it is recommended that you talk with your health care provider.

- Testosterone can cause emotional changes, including increased irritability, frustration, and anger. I have been advised that your doctor can assist me in finding resources to explore and cope with these changes.

Testosterone will result in changes that will be noticeable by other people, and that some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Your care team can assist in finding advocacy and support resources.

Prevention of Medical Complications

In order to decrease potential medical complications, take testosterone as prescribed and tell your doctor if you are not happy with the treatment or are experiencing any problems.

- The right dose or type of medication prescribed for you may not be the same as for someone else.
- Physical examinations and blood tests are needed on a regular basis to check for negative side effects of testosterone.
- Testosterone can interact with other medication (including other sources of hormones), dietary supplements, herbs, alcohol, and street drugs. Let your healthcare provider know if you are concerned about any of these potential interactions.
- Some medical conditions make it dangerous to take testosterone. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.
- You can choose to stop taking testosterone at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

Your signature below confirms that:

- Your doctor has talked with you about the benefits and risks of testosterone, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- You understand the risks that may be involved.
- You understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- You have had sufficient opportunity to discuss treatment options with your doctor. All of your questions have been answered to your satisfaction.
- You believe you have adequate knowledge on which to base informed consent to the provision of testosterone therapy.

_____ _____
Patient Signature Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Provider Signature Date

Attachment 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via Email: patd105@gmail.com

April 17, 2020

Dr. Patricia W Daugherty
Retired
Eagle Forum of Georgia
5041 Price Mill Road
Bishop, GA 30621

Re: HHS Appeal 19-0093-AA; NIH FOIA Request 51365

Dear Dr. Daugherty:

Enclosed please find a document production in connection with HHS Appeal 19-0093-AA, and the related NIH FOIA request, No. 51365. We received your request on July 9, 2019, which sought: (1) a copy of the initial grant application submitted to NIH/NICHD, including all appendices and attachments, and (2) a copy of the informed consent forms required to be signed by participants and/or parents or guardians (NOT any completed form -- just a copy of the blank forms given to participants).

With respect with part 2 of your request, the National Institute for Child Health and Human Development (NICHD) conducted a search and identified a total of 40 pages of responsive records. These are enclosed without redactions.

Please let us know if there are any questions.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosures: PDF totaling 40 pages